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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,066	12/07/2001	John J. L. Simard	CTLIMM.21CPIC	8425

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EXAMINER
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VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/026,066	Applicant(s) SIMARD ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 29-36 and 38-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 29-36, 38-52 and 54-57 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1644

### DETAILED ACTION

Claims 6-28 and 37 have previously been canceled.

Claims 29-36 have previously been added.

Claims 1-5 29-36 and 38-57 are currently pending.

In view of the Pre-Appeal conference of September 1, 2006, prosecution has been re-opened in the present application.

The following includes previously withdrawn grounds of rejection that have been re-applied in light of further interpretation of the claim limitations.

Accordingly, this Office Action is made NON-FINAL.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 recites the limitation "said first antigen and said second antigen are the same" in lines 1-2. There is no antecedent basis for this limitation in the claim. Base claim 42 recites that the antigens are different.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 29, 30, 33-35 and 38-52 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Zajac et al (145 on form PTO-1449; Int. J. Cancer [1997] 71:491-496, of record).

Zajac teaches isolated T cells that recognize the HLA-A2.1-restricted housekeeping epitope consisting of amino acid residues 27-35 of the MelanA tumor-associated antigen from melanoma target cells (Abstract and page 491, first column in particular)[claims 1, 3, 29, 30, 33-35]. Zajac teaches that

Art Unit: 1644

tumor-infiltrating-lymphocytes (TILs) were isolated from melanoma patients were able to specifically lyse target cells (pages 492-493 and Figure 2 in particular). The TILs qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Accordingly, prior to transformation of the cell line the reactive T cells were present in human serum, a carrier suitable for administration to a human. The composition satisfies the metes and bounds of the claims. Zajac further teaches specific lysis of the target cells by the HLA-A2.1 restricted T cell lines HBL and D10 (Figures 2 and 3 in particular), showing that the composition isolated from the human subject comprised at least a first and a second T cell population that were directed to epitopes which were not the same [claim 42]. The prior art teaching clearly anticipates the claimed invention.

Claims 40, 41, 56 and 57 are included because a blood sample obtained from a human subject would easily have comprised between  $10^5$  and  $10^{11}$  T cells in total.

2. Claims 1-5, 29, 30, 33, 34, 36 and 38-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kittlesen et al (79 on form PTO-1449; J. Immunol. [1998] 160:2099-2106, of record).

Kittlesen teaches isolated T cell lines that recognize the HLA-A1-restricted housekeeping epitope consisting of the amino acid sequence KCDICTDEY of the tyrosinase tumor-associated antigen from melanoma target cells (Abstract and page 2100, first column in particular)[claims 1, 29, 30, 33, 34, 36]. Kittlesen teaches that the tyrosine reactive T cells are obtained from melanoma patients whose tumors express tyrosinase (paragraph bridging pages 2100-2101 in particular) and therefore qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Accordingly, prior to transformation of the cell line the reactive T cells were present in human serum, a carrier suitable for administration to a human. The composition satisfies the metes and bounds of the claims. Kittlesen further teaches that the T cell lines were enriched in vitro from polyclonal populations [claim 3] obtained from melanoma patients by repeated rounds of stimulation with the peptide (page 2100, first column in particular) [claims 2, 4]. The prior art teaching clearly anticipates the claimed invention.

Claims 40 and 41 are included because a blood sample obtained from a human subject would easily have comprised between  $10^5$  and  $10^{11}$  T cells in total.

3. Claims 1-5, 29-32, 35 and 38-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jager et al (75 on form PTO-1449; J. Exp. Med. [1998] 187:265-270, of record).

Art Unit: 1644

Jager teaches isolated CD4+ T cell lines and an HLA-A2 restricted CTL clonal line that recognize housekeeping epitopes of the NY-ESO-1 cancer-testis tumor-associated antigen (Abstract and page 266, first column in particular)[claims 1-3, 29-32, 35]. Jager teaches that the NY-ESO-1 reactive T cells are obtained from PBL and a needle biopsy from a melanoma patient. Jager teaches that the T cells are obtained from a melanoma patient and therefore qualify as being "isolated from an immunized animal" because they were obtained from a melanoma patient that was therefore "immunized" to the antigen by the presence of the tumor in the body [claim 5].

Accordingly, prior to transformation of the cell line the reactive T cells were present in human serum, a carrier suitable for administration to a human. The composition satisfies the metes and bounds of the claims. The prior art teaching clearly anticipates the claimed invention. Claims 40 and 41 are included because a blood sample obtained from a human subject would easily have comprised between  $10^5$  and  $10^{11}$  T cells in total.


#### *Conclusion*

4. Claim 53 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.   
Patent Examiner  
November 27, 2006



DAVID A. SAUNDERS  
PRIMARY EXAMINER